

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 14-27, the only claims pending and currently under examination in this application.

Claim 21 has been amended to correct the dependency of the claim. No new matter has been added. As no new matter has been added by way of this amendment, entry thereof by the Examiner is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 14-27 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the assertedly admitted prior art or McKinney (U.S. Patent No. 3,551,273) in view of Maronian et al. (U.S. Patent No. 5,059,486) and Jacobs (U.S. Patent No. 3,857,751).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics v. Viacell et al.*, 2007 U.S. App. LEXIS 16245 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); and see *Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,'" (*citing KSR Int'l Co.* at 1741)); and see *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches; whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (*citing In re Fulton*,

391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

The present invention is directed to a method of fabricating a septum. Claims 15 and 20 depend from Claim 14. Claims 17-19 and 21-27 ultimately depend from Claim 16. Independent Claims 14 and 16 specify that the second layer (see Claim 14) and the third layer (see Claim 16) are "held in radial tension".

The Examiner alleges that the assertedly admitted prior art or McKinney disclose a three layer septum. However, the Examiner acknowledges that the assertedly admitted prior art and McKinney both fail to teach bonding the layers together while the exterior layers were in tension in order to provide the core layer in compression. To remedy the deficiencies of the assertedly admitted prior art and McKinney, the Examiner relies upon Maronian and Jacobs. Specifically, the Examiner alleges that Maronian discloses providing a layer in compression by joining a layer of elastomeric resilient material to the same while one layer was in tension and then allowed the same to relax. In addition, the Examiner alleges that Jacobs discloses the use of tension layers on either side of the core layer and that the bonding takes place subsequent to stretching the exterior layers.

The Applicants respectfully disagree and contend that a *prima facie* case of obviousness has not been established because the cited combination fails to teach every element of the rejected claims.

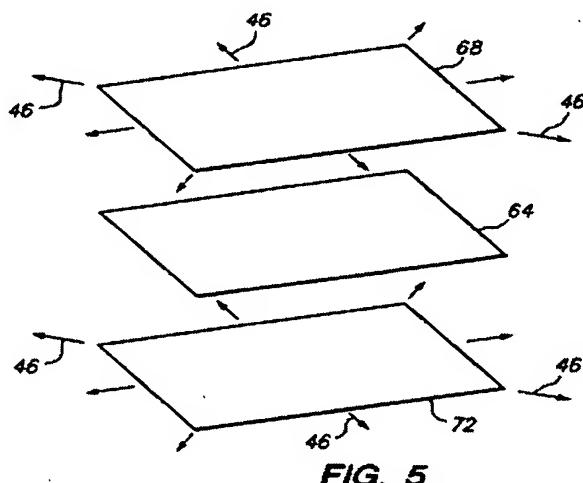
As indicated above, the Examiner acknowledges that the assertedly admitted prior art and McKinney both fail to teach bonding the layers together while the exterior layers were in tension in order to provide the core layer in compression. Thus, neither the assertedly admitted prior art nor McKinney disclose or suggest that the second and third layers are "held in radial tension", as claimed by the Applicants.

Maronian is directed to a multilayered rubber article in which the base layer is initially stretched before applying an intimately adhered overlayer of elastomeric material. Maronian specifically teaches that "the resulting article is permitted to

elastically contract to a more relaxed state." See Maronian, col. 2, lines 19-23 (emphasis added). In addition, Maronian adds that after the multilayered rubber article is cured, it is "subsequently removed from its mold and permitted to return to a relaxed state." See Maronian, col. 3, lines 52-54 (emphasis added). In contrast, the instant specification indicates that "[o]nce bonded, the outer layers 68, 72 are released. The resulting laminate will then reach an equilibrium with outer layers 68, 72 in tension and inner layer 64 in compression." See Patent Application Specification, pg. 5, lines 17-18, and FIG. 5 (emphasis added). Thus, Maronian does not teach or suggest the limitation that the layers are "held in radial tension", as claimed by the Applicants.

In addition, Maronian discloses that the thin base layer of natural latex rubber is linearly stretched. See Maronian, col. 2, lines 4-6.

In contrast, as shown with reference to FIG. 5 below, the instant invention describes a septum including outer layers (68 and 72) that are held in radial tension, as indicated by the arrows (46). See Patent Application Specification, pg. 2, lines 13-18; and FIG. 5. Consequently, Maronian does not disclose that the layers are "held in radial tension", as claimed in the present invention.



Jacobs describes a composite sheet formed from three layers of elastomeric

sheet material bonded together with intervening layers of a woven, mesh-like material held in a resiliently pre-stressed tensile condition during the bonding process. See Jacobs, col. 1, lines 18-23. However, Jacobs indicates that "the woven mesh-like layers 4 and 5 recover from their stressed condition after the bonding process has been completed." See Jacobs, col. 2, lines 30-32, and FIG. 1. Consequently, Jacobs also fails to disclose or suggest that the layers are "held in radial tension", as claimed by the Applicants.

Furthermore, Jacobs discloses that the woven mesh-like layers contain warp threads and weft threads. See Jacobs, col. 1, line 65 to col. 2, line 1, and FIG. 1. Jacobs indicates that the woven mesh-like layers may be pre-stressed in their warp directions, in their weft directions, or in both the warp and weft directions. See Jacobs, col. 2, lines 46-49. Thus, Jacobs teaches that the pre-stressed layers are linearly stretched in the warp and/or weft directions.

In contrast, with reference to FIG. 5 above, the instant invention describes a septum including outer layers (68 and 72) that are held in radial tension, as indicated by the arrows (46). See Patent Application Specification, pg. 2, lines 13-18; and FIG. 5. As such, Jacobs does not disclose that the layers are "held in radial tension", as claimed in the present invention.

Therefore, the Applicants contend that a *prima facie* case of obviousness has not been established because the cited combination fails to teach or suggest all the elements of the rejected claims. Specifically, the cited combination fails to teach or suggest that the layers are "held in radial tension". Consequently, the Applicants contend that the cited combination of references does not render Claims 14-27 obvious and respectfully request that the 35 U.S.C. § 103(a) rejection be withdrawn.

Response to Examiner's Comments

In the Office Action, the Examiner alleges that "Regarding claim 19, one skilled in the art would have understood that thermal shrinking was a well known equivalent to provision of prestressing in the art of elastomeric materials (for

example in the art of elastics it was well known to apply the elastics in a tensioned state or to apply in an untensioned state and follow this with thermal shrinkage to render the elastics elastic in the finished assembly)." See Office Action, pg. 4-5. In addition, the Examiner alleges that "Regarding claim 26, note that compression via core expansion would have been viewed as a functional equivalent to thermal shrinkage of the exterior layers. Such thermal expansion of a layer is taken as conventional in the art and it would have been within the purview of the ordinary artisan to provide such thermal expansion in order to form the laminate wherein the central layer was in compression. With regard to claim 27, note as previously discussed that expansion of the layer in order to place the layer in compression was known per se and that it was well recognized to perform expansion by heat expanding. Such was taken as conventional in the art. It would have additionally been understood as conventional in the art to chemically expand the layer as such is an art recognized equivalent means for expansion of the layer (as opposed to heat swelling of the layer)." See Office Action, pg. 5-6.

The Applicant submits that no admissions have been made and traverses the allegations made by the Examiner with respect to Claims 19 and 26-27. In particular, the Applicant traverses the Examiner's assertion that the use of chemical or thermal shrinkage, or chemical or thermal expansion as an alternative to stretching is taken as well known and conventional and would have been viewed as an alternative technique in the art.

Courts have held that the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute." *In re Ahlert*, 424 F.2d 1088, 1091, 165 U.S.P.Q. 418, 420 (CCPA 1970) (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 U.S.P.Q. 6 (CCPA 1961)); see also MPEP § 2144.03. It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *In re Zurko*, 258 F.3d 1379, 1385, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001) (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in

the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *In re Soli*, 317 F.2d 941, 945-46, 137 U.S.P.Q. 797, 800-801 (CCPA 1963); see also *In re Chevenard*, 139 F.2d 711, 713, 60 U.S.P.Q. 239, 241 (CCPA 1943); see also 37 C.F.R. § 1.104(d)(2).

As set forth above, the Examiner rejected Claims 19 and 26-27 in view of a method of applying tension which allegedly is common knowledge in the art.

Firstly, the Applicant requests that the Examiner submit an affidavit under 37 C.F.R. § 1.104(d)(2) providing support which demonstrates that chemical or thermal shrinkage, and chemical or thermal expansion as alternatives to stretching are common knowledge in the art.

Secondly, the Applicant submits that none of the references cited by the Examiner teach a method of chemical or thermal shrinking, or chemical or thermal expansion as an alternative to stretching. Maronian specifically teaches initially stretching a base layer before applying an intimately adhered overlayer of elastomeric material. Additionally, Jacobs discloses a composite sheet formed from three layers of elastomeric sheet material bonded together with intervening layers of a woven, mesh-like material held in a resiliently pre-stressed tensile condition.

The Applicant contends that if the use of chemical or thermal shrinking, or chemical or thermal expansion as an alternative to stretching was so well known in the art, either Maronian or Jacobs should have at least described the method in some form of embodiment. As such, the Examiner has failed to unquestionably demonstrate the use of thermal shrinking as being "well-known" in the art.

In view of the foregoing discussion, the Applicant submits that the Examiner's reliance on common knowledge in the art for teaching use of thermal shrinking as an alternative to stretching is improper.

CONCLUSION

In view of the amendments and remarks above, the Applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone John Brady at 408- 553-3584.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078, order number 10004031-2.

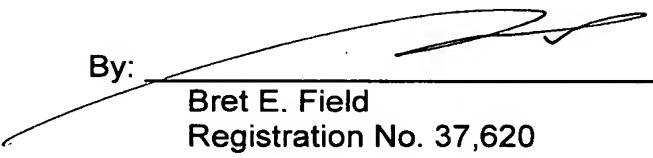
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